Mammography Quality Standards Act

Policy Statements in a Question and Answer Format

Last Updated: September 12, 1996

Table of Contents

ACCREDITATION & CERTIFICATION

Q1. What is the difference between accreditation and certification and what must my facility do to become certified?

A. Accreditation and certification are two separate processes and both are required of mammography facilities under Mammography Quality Standards Act (MQSA).

Accreditation is a process administered by an FDA-approved "Accreditation Body" and involves that body's review of a variety of aspects of a mammography facility's equipment, personnel (interpreting physicians, radiologic technologists, and medical physicists), and practices. The materials reviewed include details of the qualifications of the personnel involved in mammography, a report of the physicist's survey of each X-ray unit used for mammography, the results of dosimetry evaluations of each unit, phantom images from each unit, results from various QC tests on the mammography equipment (including the film processor), and clinical images from a number of patients. If the review establishes that, in the judgment of the accreditation body, the mammography facility personnel, equipment, and practices meet the quality standards established under MQSA, then the facility will be "accredited" by the accreditation body.

Certification is a separate process required by MQSA and is administered by FDA. FDA issues an MQSA certificate upon notification from an approved accreditation body that a mammography facility has been accredited by the body. A certification is valid for 3 years and will remain in effect and can be renewed as long as the facility remains properly accredited and successfully demonstrates during annual inspections that it continues to meet the MQSA quality standards. Only FDA-certified facilities can lawfully operate after October 1, 1994. The Health Care Financing Administration (HCFA), also, will reimburse only the mammography done at an FDA certified facility.

Facilities should not apply directly to FDA for certification. In order to be certified, a facility must first apply to, and become accredited by, an FDA-approved accreditation body. The FDA-approved accreditation bodies are currently the American College of Radiology (ACR) and the States of Iowa, California, and Arkansas. The accreditation body notifies FDA when a facility has been accredited or has successfully completed its application for accreditation. The FDA will then issue a certificate or a provisional certificate to the facility.

Q2. Our hospital unit is accredited by JCAHO. Must our mammography facility also be accredited and certified?

A. Yes. All mammography facilities must receive a certificate from FDA. To receive a certificate, the facility must first be accredited by an approved accreditation body. An approved accreditation body has demonstrated substantial compliance with the accreditation body standards established by FDA, including the establishment of a clinical image review program conducted by qualified personnel. Currently, only the American College of Radiology and the States of Arkansas, California, and Iowa are approved accreditation bodies. JCAHO accreditation is different from FDA certification under MQSA.

Q3. ***I have a mammography facility, but do not wish to apply for or receive accreditation from the American College of Radiology. Are other options available? If so, what are they?***

A. Presently, the American College of Radiology (ACR), the States of Iowa, California, and Arkansas are the only approved accreditation bodies. You may apply to Iowa, California, or Arkansas for accreditation only if your facility is in that state.

Q4. ***Will the FDA ever serve as an accreditation body?***

A. FDA has no plans at this time to serve as an accreditation body.

Q5. ***What would happen if a facility does not apply for accreditation?***

A. As of October 1, 1994, all mammography facilities since October 1, 1994 must be certified by the FDA. If the facility does not have an FDA certificate, the facility cannot lawfully provide mammography. Facilities without a provisional or full certificate cannot operate lawfully. MQSA provides various sanctions that can be applied to facilities operating unlawfully. Such facilities will also have to be concerned about explaining the lack of a certificate to the women they serve, the inability to obtain Medicare reimbursement for mammography, and increased liability to malpractice suits.

Q6. ***If I am starting a new mammography facility, how much time do I have to become accredited? (I have an ACR application, but don't yet have a unit in the facility.)***

A. A facility must have a certificate from FDA in order to lawfully provide mammography services. You should apply for accreditation first. When the accreditation body accepts your application for review, it will notify FDA, and FDA will issue you a provisional certificate. This 6-month provisional certificate will

permit you to begin providing mammography services. Before use on humans, all X-ray units should pass an equipment evaluation to demonstrate that they are operating properly. When these two steps have been completed, you can then collect the clinical images and other data that will be needed for the accreditation process to be completed. Once the accreditation process has been successfully completed, the FDA will issue you a 3-year certificate. Remember, the provisional certificate is good for only 6 months so you must act promptly to complete the required steps in the accreditation process, so that accreditation can be completed within that period.

Q7. If I receive a provisional certificate, will it indicate provisional on it?

A. No. A date that is 6 months from the time the accreditation body accepts your application will be the indicator that the certificate is provisional.

Q8. Does the FDA certify mammography X-ray units or facilities?

A. MQSA certification is facility based rather than unit based. Therefore, all equipment and personnel in the facility involved in the provision of mammography services must meet the quality standards promulgated by the FDA regulations.

Q9. My facility is located in a state that has been approved by FDA as an accreditation body. Must we be accredited by the state or can we continue to be accredited by the ACR?

A. You can be accredited by either one, and you will receive your MQSA Certificate from the FDA. However, state law may require every facility to have a State accreditation or State certification. These state requirements are independent of MQSA, and you must satisfy all such regulations.

Q10. Our facility applied to an FDA-approved accreditation body. Our accreditation body notified us that our application is complete for review. I am concerned that the accreditation process will not be completed in time for us to receive our mammography certificate. Will we be able to continue to operate lawfully if we do not have a certificate?

A. Facilities that are in the process of accreditation will be issued a provisional certificate to give them time to complete the process. Such provisional certificates will be issued only if the accreditation body has reviewed the facility's initial application and has informed FDA that they consider the application acceptable to permit the facility to go on to the next accreditation stage. The provisional

certificate will allow the facility to continue to operate lawfully for up to 6 months, while the accreditation and certificate processes are completed. Because this time period is limited, a facility with a provisional certificate must promptly provide all required information to its accreditation body. Facilities cannot operate lawfully beyond the 6-month period of provisional certification. If an accreditation process is not complete by that time, a facility may apply to FDA for a 90-day extension. (See extension policies, page 13) for applicable circumstances. Please note that this discussion is to be added.)

Q11. We were accredited by an FDA-approved accreditation body, but we still have not received our certificate. What should we do so that we can lawfully provide mammography services?

A. You need to contact the FDA. The FDA will fax or send you an interim acknowledgment. You should prominently display this interim acknowledgment until you receive your FDA Mammography Facility Certificate.

Q12. Our group practice interprets mammograms sent to us by other facilities under a contractual arrangement. This is the only service that we provide in the mammography area. Does my group practice need an FDA certificate to interpret mammograms?

A. No. The basic requirement established by MQSA is that any facility that produces, processes, or interprets mammograms after October 1, 1994, must have an FDA certificate to continue to operate lawfully. Generally, however, where procedures such as processing and interpretation of the films are performed in a location different from where the mammography is performed, the facility performing the mammography will be responsible for obtaining a certificate.

There is no mechanism at the present time for accrediting and certifying an organization such as yours. FDA's policy is that partial providers, that is, groups such as yours that provide only part of the services required for mammography, will be certified as part of a "system" for producing, processing, and interpreting mammograms.

The provider of some component of that system that performs mammography must take the lead in obtaining a certificate. FDA expects that the owner of an X-ray unit or units will apply for accreditation and receive a certificate. The application for accreditation must show that all components of the system used to produce, process, and interpret mammograms meet the MQSA requirements. If one or more of the facilities for which you interpret mammograms is applying for accreditation and certification, your responsibility will be to provide them with the information

necessary to prove that the physicians in your group meet the MQSA quality standards requirements for interpreting physicians.

When the facilities performing mammography receive their certificate, you will be included for the purpose of interpreting mammograms for that facility. If you interpret mammograms for several facilities, your group will be included under several certificates. Conversely, if one of the facilities for which you interpret mammograms is not certified, then it would be unlawful for them to continue to produce mammograms. Although, as mentioned, the owner of the X-ray unit(s) will probably take the lead in obtaining the certificate in most cases, any partial provider in a "system" can seek the required certificate.

Your group practice could apply for accreditation and receive the certificate, as a part of a system. In that case, your practice would be **responsible** for assuring not only that your practice meets the MQSA quality standards for interpreters, but also that the facilities that produce and process the mammograms for your interpretation meet the quality standards that apply to them. Your practice would also be responsible for passing the review of clinical images from each facility that produces images for your interpretation, and for meeting the other requirements for accreditation. Finally, as a certificate holder, you would be responsible for paying an annual FDA MQSA inspection fee.

Q13. Are there other situations besides interpreters in group practices to which the previous answer applies?

A. Yes. The previous answer applies to all partial providers, that is to any organization that provides some but not all of the services necessary for the production, processing, and interpretation of mammograms.

One example is a hospital, clinic, or private office that agrees to have a mammography unit placed on its premises by a service company. In such cases, the service company usually provides the technologists and maintenance for the unit and may also provide interpretative services and even processing. The hospital, clinic, or private office may provide only for intakes of the examinees and transmittal of the results back to them. Again, the provider of some component of this system must take the responsibility of obtaining a certificate. If this is not done, all partial providers including the facility at which the machine is located will be unlawfully providing mammography. Operators of mobile units are also often partial providers, that is, their services may be limited to producing and processing the films or even to just producing them. Again, the mobile units must be certified as part of a system to continue to lawfully operate and the operator of the unit, or the provider of some other component of the system must take the steps required to obtain accreditation and certification.

Q14. Are we required to obtain a second certificate when the interpreting radiologist is located at an off-site FDA-certified facility?

A. You should have a certificate for each site with a patient/examinee reception area. FDA can issue copies of your original certificate on request. You do not need a certificate specifically for the site of the interpreting physician(s) if they are not at the facility with the patient/examinee reception area. However, you would be responsible for assuring that all mammogram interpreters meet the MQSA quality standards for interpreters.

Q15. We presently perform mammography in two separate locations. Although we perform mammography at both locations, we interpret the mammograms at one of the two. Do we need two original certificates?

A. Perhaps. Sites in the same building or a short distance apart, under the same ownership and management, may qualify as a single facility. The interpretation site is not a determining factor.

Q16. We have an ACR-accredited mobile unit. Our second site is an outpatient center in the hospital. Do we need two separate certificates?

A. The mobile unit should be certified as part of the hospital's overall "mammography facility," a facility that contains multiple X-ray units. The hospital should request an additional (duplicate) certificate to use with the mobile unit.

Q17. My facility performs mammography only for special purposes (localization, biopsy, specimen radiography, or research). Do we need to be accredited and certified?

A. Not at this time. Although these procedures do involve radiography of the breast, the current state of knowledge does not permit the development of acceptable quality standards for these procedures, nor are there mechanisms for review of the clinical images that result from these procedures. For the immediate future, FDA will not expect facilities that conduct radiography of breast only for these special purposes to meet the specific requirements of MQSA. Look for more information on this in future issues of *Mammography Matters*.

Q18. My facility has a mammography unit that is used only for special purposes (localization, visualization of breast implants, biopsy, specimen radiography, or research). Must we include it in our accreditation and certification efforts?

A. At this time you need not include any unit or personnel that are involved in conducting radiography of breast only for these special purposes in your accreditation application. When your facility undergoes an MQSA inspection, you will need to provide proper attestation that such equipment and personnel are used only for these special purposes.

Similarly, personnel who are involved in performing screening and diagnostic mammography would obviously have to meet MQSA personnel requirements through the accreditation process, even if those employees were also involved in performing the special purpose procedures. All units **ever** used in routine screening and diagnostic mammography would have to meet all applicable quality standards, undergo the accreditation, and would be covered under your certificate.

Q19. My facility has a mammography unit that is used mostly for special purposes (localization, biopsy, specimen radiography, or research) but is occasionally used for routine screening or diagnostic mammography. Must we include it in our accreditation and certification efforts?

A. Yes. Any X-ray units or personnel involved **even occasionally** in routine screening or diagnostic mammography have to meet the MQSA quality standards. They would have to be included in your accreditation application and would be covered under your certificate.

Q20. We use mammography units only for training technologists. Does our facility need an FDA certificate?

A. It depends. Assuming that your training involves the examination of patients, rather than using only simulations or phantoms, your facility would be considered a mammography facility and would need a certificate. If no live human subjects are ever exposed with this equipment, your facility would not be considered a mammography facility and would not be subject to the requirements of MQSA.

Q21. In a college-based radiology program with a mammography curriculum, would the facility be in non-compliance for letting student technologists show competency in performing mammography on live patients?

A. No. There is nothing in the MQSA or FDA's regulations that will interfere with training in mammography. Student technologists can receive classroom and practical training in a variety of ways. Student technologists who do not yet meet the requirements established under MQSA may perform actual examinations as part of the training so long as another technologist **who does meet** the MQSA requirements is present in the room to supervise and, if necessary, correct the

student in the conduct of the examination. But the facility would have to be FDA certified.

Q22. Only some of the units in our facility have been accredited. Can our facility become certified even though all of our units are not accredited? Can we use non-accredited units?

A. Certification by FDA is facility based not unit based. You may, therefore, receive certification even though all your units are not accredited. However, if you **ever** plan to use any unit that is not included in your accreditation, you must promptly contact your accrediting body and follow its advice (which may involve a formal application for accreditation of any previously non-accredited unit or newly acquired unit). If the accreditation body decides that you have satisfied its requirements of use of new units (or any other unit that was not included in the accreditation) and informs FDA of its decision, FDA will include the said unit under the existing certificate.

A loaner, demonstration, or prototype mammography unit may be used for a limited period before a facility is required to apply to have the unit(s) included under its accreditation. Loaner units (placed in a facility while the facility's unit is undergoing in-house or off-site repair) may be used for 30 days. This period may be extended upon written verification from a repair service that there is a legitimate cause for repairs to exceed 30 days. Demonstration units under consideration for purchase by a facility and prototype units that are being tested prior to marketing can be used for up to 90 days. A facility must contact its accrediting body and follow its advice, prior to use of any demonstration unit on patients. MQSA inspectors will need to see this documentation during any inspection.

Q23. What happens when a facility purchases a new mammography unit? Will the new unit need accreditation? How can you get it accredited if you can't use it until it is accredited?

A. All equipment and personnel in the facility involved in the provision of mammography services must meet the quality standards. In an already certified facility, a newly installed unit can be used only after satisfying the requirements of the accrediting body. You must immediately contact your accrediting body and follow its guidelines for newly installed mammography unit before use on patients.

Q24. I have a mammography unit that our medical physicist says will be out of compliance with MQSA equipment regulations for source-to-image distance (SID) in the fall of 1996. I need to know for how long I can continue to use this machine before it needs to be fixed or replaced.

A. No minimum SID is specified under the current interim standards. The final standards, however, may specify a minimum SID, and once those standards become effective, the equipment will have to meet them. The final standards, however, will not be in effect before 1997, so your equipment is in compliance at least until then.

Q25. Must all units used for screening and diagnostic mammography in a facility be accredited by an accreditation body?

A. Yes. All units must be included in the facility's accreditation by an approved accreditation body.

Q26. I've heard that xeroradiography is banned by MQSA. Is this correct?

A. No. The interim regulations specifically cover xeroradiography units and state that the average glandular dose delivered during a single cranio-caudal view of a phantom of specified thickness and composition shall not exceed 4.0 milliGray (0.4 rad) per exposure for xeromammography procedures. Your accreditation body will accredit facilities with xeromammography units that meet the dose limit and other accreditation requirements. Be aware, however, that some states have banned or intend to ban xeroradiography for mammography.

Q27. How will FDA synchronize its certification period with a facility's accreditation period?

A. The FDA certification will expire 30 days after the expiration date of the most recently accredited unit (if accredited prior to October 1, 1994).

The initial certificate issued to a facility will expire 30 days after the date on which the facility's accreditation expires. However, if a facility wishes to continue to lawfully provide mammography services, it must be reaccredited before the initial certificate expires. When the accreditation body informs FDA that the facility has been reaccredited, the facility will receive a new FDA certificate. Because this new certificate also will expire 30 days after the accreditation expires, this certificate (and all subsequent certificates) will be valid for 3 years.

Q28. What requirements must be met by a department transferring operation from an in-patient facility to a newly built out-patient facility? We are ACR-accredited.

A. You must discuss with your accreditation body the steps necessary to retain your accreditation. It may be necessary to go through the entire accreditation process again.

Q29. Our mammography units are ACR accredited, and we have received our FDA certificate. Are we allowed to promote our breast cancer center as "FDA certified?"

A. Once you receive your certificate from FDA, you may tell anyone you wish that you are an FDA-certified mammography facility, which means that you can include this information in any promotional material. Of course, to keep your FDA certification, you must pass the annual MQSA inspection and keep practicing quality mammography.

Q30. If FDA withdraws its approval of my accreditation body, how will that affect my certification?

A. Your certificate will remain in effect for 1 year or until you receive accreditation by a new body, whichever is shorter. When you are accredited by a new body, you will receive a new certificate. If you have not been reaccredited at the end of 1 year, it will be unlawful for you to continue to provide mammography services.

Q31. My facility has received an FDA certificate. Now what do I have to do?

A. You must prominently display your certificate in a location where it can be seen by those who visit your facility for mammography services. You must continue to comply with the MQSA quality standards and permit annual inspections and audits of your facility, and you must correct any deficiencies noted during these inspections and audits. Finally, you must become reaccredited at the frequency required by your accreditation body and comply with any other actions required by that body as conditions for maintaining accreditation. As long as your facility remains in compliance with these MQSA requirements and continues to be accredited, your certificate will be automatically renewed at the end of each certification period.

Q32. As a family practice physician who refers her patients for mammography, how can I determine whether the facility to which I refer my patients has been properly certified?

A. As of October 1, 1994, mammography facilities that have been properly accredited have received their certificates. You, and any of your patients, can determine whether a facility is certified by checking to see it has an FDA-issued certificate

prominently displayed on the premises. Information identifying certified facilities in your area may also be obtained from the National Cancer Institute by calling their 1-800-4-CANCER number.

Q33. My facility has more than one examinee reception area. Where do we display our certificate?

A. All facilities must prominently display the mammography facility certificate where it can be viewed by mammography examinees. If your facility has more than one examinee reception area and you wish additional certificates for examinee viewing, please contact the FDA as soon as possible with a description of your situation so that we can determine whether additional certificates are appropriate.

Q34. Our facility has multiple mammography departments, each with its own reception area. How should we display our FDA Mammography Facility Certificate?

A. FDA certification is facility based. Therefore, if each of the departments in your facility is included as part of a facility's accreditation and each has its own reception area, then your facility may request additional certificates for display in the separate reception areas. These additional certificates will share a unique facility identification number because each of these sites were included as part of the facility-based certification.

If your facility has multiple sites that have each applied for and received separate accreditation, each of these certified facilities (locations) would receive a separate certificate with its unique facility identification number. Additional certificates could also be obtained for these facilities, if needed, for their multiple patient waiting areas.

Q35. Our facility provides mammography services to a large Spanish-speaking population. Can we obtain an FDA certificate translated into Spanish?

A. FDA will issue an additional certificate translated into Spanish for those facilities serving a Spanish-speaking population. If you want this additional certificate, please notify us via fax or letter. You must prominently display the Spanish-language certificate along with your English-language certificate where it can be viewed by mammography examinees.

Q36. My mammography facility received two FDA Mammography Facility Certificates. We were originally accredited by the ACR and subsequently by our State. FDA

issued two certificates, each with a unique facility identification number. Which certificate should we retain?

A. You have the option as to which accreditation body you want to be accredited by or, if you wish, you may be accredited by both. FDA allows the facility the option to choose the accreditation body. However, you should not have more than one certificate or facility identification number, and your facility should return the remaining FDA certificate to FDA with an explanatory cover letter. You should retain the FDA certificate that shows the name of the accreditation body that accredited your facility first.

Q37. Our facility will no longer be providing mammography services. What should we do with our FDA Mammography Facility Certificate?

A. You must return your original certificate to the FDA.

Q38. Our facility has moved. Can we still use our FDA Mammography Facility Certificate? If not, what should we do to obtain a new certificate?

A. You should notify your accreditation body of your change of address. The accreditation body will direct you regarding any additional information and/or testing they may require. Once you have satisfied its requirements,. the accreditation body will inform FDA of your new address. FDA will issue you a new certificate reflecting your new address. Meanwhile, you must prominently display your original certificate, replacing it upon receipt of the newly issued one. When you receive your newly issued certificate, you must return your original certificate to the FDA.

Q39. Our facility has changed its name, but we have the same owner, personnel, and equipment. Can we still use our FDA Mammography Facility Certificate? If not, what should we do to obtain a new certificate?

A. You should notify your accreditation body of your change of name. Once you have complied with its requirements regarding the process the accreditation body will inform FDA of your new facility name. FDA will then issue you a new certificate reflecting the new name. Meanwhile, you must continue to prominently display your original certificate, replacing it upon receipt of the newly issued one. When you receive your newly issued certificate, you must return your original certificate to the FDA.

Q/A on Extension and Reinstatement will be added.

INSPECTIONS

Q1. Does MQSA require inspections? How often?

A. Yes. Annual inspections for compliance with the quality standards are required for all facilities. In addition, facilities may receive on-site visits from their accreditation body or "audit" inspections by FDA personnel. MQSA requires FDA to audit a certain number of facilities that have been inspected by State agencies under contract to FDA. These inspections are called audit inspections, and are designed to assure the quality of the State inspections. To the extent possible, the FDA inspector performing this audit function will accompany the State inspector at the time of the scheduled annual inspection. However, there may be a need, at times, for FDA audit inspections to take place at a different date than the annual inspection.

Q2. What is a follow-up reinspection?

A. A follow-up reinspection is an inspection where FDA will reinspect a facility to evaluate whether the facility has corrected noncompliances found during the annual inspection. FDA may conduct a follow-up reinspection for one of several reasons. When Level 1 noncompliances are found, a reinspection may be conducted to evaluate correction of the problems found. A reinspection may also be conducted if a facility has not responded when required by FDA or has not corrected problems from the annual inspections.

Q3. Will there be fees associated with the annual MQSA inspections?

A. Yes, mammography facilities will be charged an annual inspection fee under MQSA. Facility inspection fees are based on the number of mammography units used by the facility. The following fees will be assessed for facility inspections conducted in fiscal year 1995:

Annual inspection	$1,178 for the first unit, plus $ 152 for each additional unit
Follow-up inspection	$ 670

Each facility will receive a bill after the inspection, and the fee will be due in 30 days with interest and penalties accruing after that time. If a reinspection is required to verify the correction of a serious noncompliance with MQSA quality standards, there will be a separate fee and billing for that reinspection. An

inspection fee bill will be mailed to each facility separately. The only facilities that will not be charged an annual inspection fee are "government entities." A definition of government entity was published in the Federal Register together with the announcement of the actual inspection fees for 1995 (see also Question 4). A facility may use the form included with the inspection fee bill when it is mailed to the facilities to attest to its government entity status. If FDA accepts the facility's assertion, then the facility will not be required to pay the inspection fee. FDA may require additional supporting documentation to verify the government entity status of a facility.

Q4. What is the definition of a government entity?

A. A government entity is a mammography facility subject to inspection that meets either of the following criteria:

(1) The facility is operated by any Federal department, state, district, territory, possession, federally recognized Indian tribe, city, county, town, village, municipal corporation, or similar political organization or subpart thereof; or

(2) The facility provides services under the Breast and Cervical Cancer Mortality Prevention Act of 1990, 42 U.S.C. 300k*et seq.*, and at least 50 percent of the mammography screening examinations provided during the preceding 12 months were funded under the statute.

Q5. Who will conduct the inspection?

A. The annual inspections will be conducted primarily by state radiation control personnel under contract to FDA. In federal facilities, and in states where an adequate number of state personnel are not available, the inspections will be conducted by FDA personnel. In all cases, the inspectors will be trained and tested for proficiency by the FDA.

Q6. What minimum qualifications must a MQSA inspector have in order to be accepted into FDA's MQSA inspector training program?

A. The candidates must have one of the following sets of qualitications.

1. A Bachelor's degree (B.A. or B.S.) with a major in physics or radiologic technology or with a major another field with at least 30 semester hours in science at the college level; *or*

2. Certification by the American Registry of Radiologic Technologists, or general or unrestricted State licensure to practice diagnostic radiologic technology, *and*
   at least two years of experience in diagnostic radiologic technology or radiological health work, *or*

3. An Associate's degree in science, or at least two years of college level courses with a minimum of 16 semester hours in science at the college level, *and*
   at least two years experience in diagnostic radiology or radiological health work.

Q7. What is the scope of MQSA inspection?

A. The scope of the MQSA inspection will be limited to specific tests and record reviews that have the most direct bearing on facility performance and mammographic quality, namely:

- Equipment performance, including image quality and dose
- Technologist and physicist quality control/quality assurance (QC/QA) tests and tasks
- Medical audit and outcome analysis records
- Medical records (mammography reports)
- Personnel qualification records.

Q8. Which physical tests are included in the MQSA inspection?

A. The physical tests are:

1 - Collimation Assessment consisting of two parts:
   a. X-ray field / image receptor alignment
   b. Image receptor / compression device alignment
2 - Entrance Skin Exposure and Exposure Reproducibility
3 - Beam Quality (HVL) Measurement
4 - Mean Glandular Dose
5 - Phantom Image Quality Evaluation (including phantom scoring)
6 - Processor Evaluation
7 - Darkroom Fog.

Q9. How long will an inspection take?

A. It is expected that the inspector will normally spend approximately 6 hours in each facility, less than an hour of which will involve measurements with the mammography unit and processor, with the rest of the time devoted to record

review. A longer time may be required if a facility has several units or if the facility does not have the necessary records or information readily available. FDA has sent materials to each facility about how to prepare for inspections so that inspections can be conducted efficiently with minimum disruption to patients and personnel.

Additional time will be required if the state inspector also conducts a state inspection during the same visit for state requirements that are more stringent than those of MQSA.

Q10. Will a facility be notified before the inspection?

A. In most cases, the facility will receive a verbal notice at least 5 working days before the inspection date. At this time, the inspector will work with facility personnel to schedule a mutually agreeable inspection date. The verbal notice will be confirmed by a written notice. (The notice will be faxed to those facilities with fax equipment; other facilities will receive a notice in the mail.)

Q 11. What can I do to help prepare for an inspection? Can we prepare some records in advance?

A. Absolutely. The records the inspector will need to see are QA/QC records, medical audit and outcome analysis records, the physicist's survey report, personnel qualification records, and examinee medical records. To minimize time spent searching for documents during the inspection, the facility is encouraged to organize these records in one location and one binder or file whenever possible.

Q12. Regarding the QA/QC records, which records are included and how far back should they be made available?

A. The QA/QC records listed below should be available. The inspector will review past records (1) over the indicated period listed for each, or (2) back to the date of the original accreditation, or (3) for facilities with provisional certificates, back to the date the provisional certificate was issued, whichever date is the most recent.

- Records (for the previous 12 months or back to the date of the original accreditation if accreditation is less than 1 year) of the technologist's 11 QC tests/tasks listed below [Ref. 1992 & 1994 ACR QC manuals]:
    1. Darkroom cleanliness
    2. Processor quality control
    3. Screen cleaning
    4. Viewboxes and viewing conditions
    5. Phantom images

6. Visual check list
7. Repeat analysis
8. Analysis of fixer retention in film
9. Darkroom fog
10. Screen-film contact
11. Compression

- Sensitometric film strips from the previous 30 days using the processor that was used to process mammograms
- Phantom images for the previous 12 months
- Images from film/screen contact and darkroom fog tests for the previous 12 months
- The most recent annual medical physicist's survey report.

Q13. What about QA/QC records for mobile units?

A. The requirements for mobile radiographic units are the same as for fixed units. This means that the information outlined in the answer above should be available. In those cases where some of the QC testing is performed at remote sites, copies of these records should be maintained by the mobile provider and be available to the inspector.

Q14. What about records for medical audit and outcome analysis?

A. Each facility must have a system to track positive mammograms and correlate them with biopsy results. Positive mammograms are those where malignancies are suspected and biopsies are recommended. This system need not be computerized. The minimum biopsy data, if obtainable, should indicate if the specimen was benign or malignant. If the facility has a written tracking and medical audit policy statement, it can be presented to the inspector. The inspector will examine the facility's tracking system and inquire as to how the facility obtains biopsy results. The inspector will also request to see examples of biopsy results from patients with positive mammograms.

Q15. Are facilities required to have internal communications records or records of QA team meetings as a part of the service records ?

A. Facilities are encouraged to maintain internal communications regarding problem areas that affect the quality of mammography and to keep records of such communications or meetings in their QA manual as a good standard practice, but it is not a requirement. Facilities will not be cited for not keeping such records.

Q16. What personnel qualification records will be required?

A. For the interpreting physician:

(i) A valid state license to practice medicine, *and*

(ii) (a) Evidence of certification by the American Board of Radiology (ABR), American Osteopathic Board of Radiology (AOBR), or Royal College of Physicians and Surgeons of Canada (RCPSC) in diagnostic radiology [original or copy of certificate, letter from one of the above boards or college, or a letter from the American College of Radiology (ACR) specifically confirming that the physician is board certified by the ABR or the AOBR, will be acceptable documentation]; *or*

(b) Two months of documented training in mammography; *and*

(iii) Documented 40 hours CME in mammography; *and*

(iv) Initial experience:
Documented experience in reading/interpretation of mammograms from at least 240 patients in the 6 months preceding the facility's application to an accreditation body or during any 6 months prior to October 1, 1994, or, after October 1, 1994, in any 6-month period under the supervision of a qualified interpreting physician; *and*

(v) Continuing experience and education:

(a) Documented continuing experience showing that the required average of at least 40 examinations per month (when averaged over the 24 months prior to the inspection date) have been read/interpreted by the individual; *and*

(b) Documented average of 5 CME credits/year in mammography. This average will be required beginning 3 years from October 1, 1994, or the date of initial qualifications, whichever is later. If documentation is not available, proper attestation will be acceptable for items (iii) and (iv) for records dated up to October 1, 1994.

For the radiologic technologist:

(i) A valid State license or certificate from the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT); *and*

(ii) Documented specific mammography training or until October 1, 1996, 1 year experience in performing mammography; *and*

(iii) A documented average of 5 CEUs per year in mammography. This average will be required 3 years from October 1, 1994, or from the date of initial qualifications whichever is later. If documentation is not available, proper attestation will be acceptable for item (ii) for records dated up to October 1, 1994.

For the medical physicist:

(i) (a) State license/approval; *or*

(b) Certificate with a specialty in diagnostic radiological physics or radiological physics from the American Board of Radiology (ABR) or American Board of Medical Physics (ABMP);*or*

(c) Before October 27, 1997, have a masters or higher degree in physics, radiological physics, applied physics, biophysics, health physics, medical physics, engineering, radiation science, or in public health*with* a bachelor's degree in physical sciences;*and*

(1) 1 year documented training in diagnostic radiologic physics,*and*

(2) 2 years documented experience in mammography surveys;*and*

(ii) Documented average of 5 CEUs per year in mammography. If documentation is not available, proper attestation will be acceptable for (i)(c)(1) and (2) for records dated up to October 1, 1994.

Q17. What is the actual starting date for CME credits?

A. The starting date for CME credits is October 1, 1994. However, FDA will not declare a noncompliance under MQSA for failure to meet this requirement until at least 3 years after October 1, 1994, or after the date of completing the initial qualifications, whichever is the latest.

Q18. What about medical records requirements?

A. The records the inspector will ask to see include examinee permanent records of mammography reports. The inspector will inquire as to where and how the facility maintains these records and will randomly select examinations that were performed after October 1, 1994, to assure that both films and reports are being retained at the facility or at another identifiable location.

Q19. How are electronic medical reports inspected?

A. In facilities where the medical records are computer generated and stored, there may not be any "hard copy" to review. In those instances where a "hard copy" does not exist, the inspector will randomly review reports on a monitor. Facility personnel shall provide access to a monitor and the electronic medical reports for the inspector.

Q20. Are there any differences between the storage and retention of electronic medical records versus non-electronic ("hard copy") medical records?

A. No. Electronic medical records and "hard copy" records<u>do not</u> have to be stored in the same place as the actual mammography films. Retention times for electronic

medical records are no different than for non-electronic ("hard copy") medical records. (For additional information on medical record retention refer to Q2 under Recordkeeping).

Q21. Are there requirements regarding individual mammography reports?

A. Yes. The facility should be prepared to show the inspector samples of reports that were sent to referring health care providers and samples of lay summaries of positive mammograms that were sent to self-referred examinees, if applicable. The inspector will also randomly select and examine a few reports dated after October 1, 1994, to verify that the reports contain the physician's name (at a minimum first initial and last name) and an interpretation of the examination. The facility should also be prepared to explain its system or procedures for communicating test results to referring physicians and self-referred examinees.

Q22. What will the inspection process be like?

A. The inspector will meet first with the facility's responsible parties and obtain or verify some preliminary information regarding the facility. The inspector will then briefly go over the inspection agenda and will be flexible as to which area to cover first, depending on the facility's schedule. When the inspection is completed, the inspector will meet again with the facility's responsible parties to review inspection results.

In general, inspectors will try to hold any questions they may have to the end of the inspections, to allow the facility personnel to attend to their normal duties for most of the day. Also, the inspectors (in most states) will leave a preliminary report of the inspection with the facility.

Q23. I have four units at two separate sites. Will all four units be inspected separately and have separate inspection fees?

A. Like the certification process, inspections are facility based and not unit based. Inspections will be based on the number of unique certificates (not duplicate certificates). Thus, two different addresses and two unique certificates will equal two separate inspections and two inspection fees (including fees for additional units at the two sites if appropriate).

Q24. Will there be an inspection fee whether the inspector visits the site or not?

A. No. An inspection fee will only be charged if an on-site inspection is conducted.

Q25. Must my facility be inspected before I receive certification?

A. No. Inspections are to determine continued compliance with the certification requirements and are not a predicate to obtain a certificate.

Q26. What is the difference between a MQSA inspection, an audit inspection, an on-site visit, and a medical physics survey?

A. A MQSA inspection occurs when an FDA inspector (or a state inspector under contract to the FDA) goes to a facility and conducts an evaluation of a mammography facility to determine compliance with the MQSA quality standards. Each inspector must receive special training from the FDA and pass examinations to become certified to conduct inspections.

An audit inspection is performed by specifically qualified FDA personnel (MQSA auditors) to oversee the quality of state and FDA inspections under MQSA. FDA auditors must perform inspections of facilities that have been inspected by state and FDA inspectors in order to ensure that the inspections are conducted in an appropriate manner. This audit inspection will usually take the form of a joint inspection, where an FDA auditor would accompany the state or FDA inspector during the regularly scheduled annual inspection. At other times, the FDA may choose to conduct an independent audit inspection, where an FDA auditor will inspect a facility that had been previously inspected by a state or FDA inspector.

Each approved accreditation body must perform a certain number of site visits to facilities it accredits to ensure that those facilities meet the standards of the accreditation body. An on-site visit is made by an accreditation body.

As part of the accreditation process and, annually, after accreditation has been granted, each facility must have a medical physics survey of their mammography facilities. These surveys must be conducted by an individual who meets the qualifications of a medical physicist under the MQSA standards. The survey consists of tests conducted on the X-ray system, film processor, film cassettes, and an evaluation of the facility's technologists quality control program.

Q27. Will ACR continue to conduct site visits?

A. All approved accreditation bodies are required to conduct a sufficient number of on-site visits to assess overall compliance with their standards. Thus, the ACR will continue to conduct on-site visits of a sample of the facilities that it accredits; the state accreditation bodies will do likewise.

Q28. Does a mammography screening facility that participates in the HCFA Medicare program need two inspections—one for Medicare and one for MQSA?

A. No. Beginning October 1, 1994, HCFA will reimburse for Medicare if a facility is FDA certified. On that date, MQSA inspections began and HCFA inspections ended.

Q29. I am confused about two inspections: State inspection and MQSA inspection, and if there will be fees associated with each. Should we expect to have to pay for all of this next year?

A. Your facility is subject to both state and MQSA inspections. You need to contact your State program about any state inspection and fees. All facilities are to be inspected within the first year of MQSA. If you are to have an MQSA inspection, it will be scheduled in advance and a bill will follow.

Q30. What happens after the inspection is complete?

A. When all tests and reviews are completed and when all remaining questions have been answered, the inspector will review the results of the inspection with the facility's responsible parties and either leave a summary of test data collected and observations made during the inspection or mail the summary to the facility within a few days.

Q31. Will the facility be able to resume operations as usual after the inspection?

A. Normally, yes. If no deficiencies were found during the inspection that would pose an immediate threat to the health and/or safety of patients, the facility operations may generally continue. Under state jurisdiction, the state inspectors may have the authority to direct the facility to discontinue operations for lesser violations.

Q32. What happens when deficiencies are found?

A. In some cases after receiving a summary of deficiencies, the facility will be required to respond to the FDA within 30 days regarding how it has corrected the deficiencies. In other cases, the facility will be expected to correct the deficiencies, but will not be required to submit a written response. In the latter case, the corrections will be evaluated at the next annual inspection. If major deficiencies are found, the facility will receive a letter from the FDA containing guidance on how to respond, and follow-up inspections may be conducted to verify the corrections of the deficiencies (there will be a separate fee of $670 for such a follow-up

inspection). All deficiencies are expected to be corrected as soon as possible, and when it is determined that the deficiencies found could affect mammographic quality directly, the deficiencies should be correctedimmediately. Facilities that continue to operate under deficient conditions are subject to certificate suspension and other sanctions, including civil money penalties.

Q33. If a facility is found to be using a cracked, broken, or defective phantom for their regular and monthly QC work while borrowing phantoms from other facilities to get through their accreditation process, what does the inspector do about it?

A. When a facility is using a cracked or broken phantom for their phantom image QC testing, the first course of action for the inspector would be to answer "No" ("N") (since the use of such a phantom clearly constitutes an uncorrected problem) to the inspection question "C/A documented?", which is located on the 'Phantom QC & X-Ray Unit' screen under the 'Quality Control' section of the 'Records' portion of the inspection software. Additionally, this information would be entered into the 'Remarks' section which prints out to the facility the 'General Inspection Data' screen. The facility will also be advised to acquire a new phantom.

Q34. Can facilities use an older version of ACR phantom?

A. No. They should contact ACR (or the vendor where it was purchased) to order a replacement with a current phantom.

Q35. What is the "C" answer that inspectors sometimes use in inspection questions?

A. The options of using the "C" answer for some of the inspection questions have been made available as "tools" to be used by the inspectors when, in their judgement, such flexibility is warranted. Inspectors are not required to use these tools if they believe that the facility is abusing the system.

These tools were intended primarily for use during the initial transition stage when the facilities, inspectors, and FDA are getting used to the requirements and making adjustments in the procedures to fit situations discovered during inspections. As we complete the first round of inspections and move into the second, we expect that these tools would be used less frequently, as there would be fewer valid reasons for facilities being unaware of what was required of them. However, we expect to keep these tools available because there still will be situations when their use would be valid. For example, State licensing boards sometimes fall months behind in sending renewals of licenses to medical personnel. The option of using the "C" answer in such a situation would avoid penalizing individuals for problems that were not their own.

PERSONNEL

Q1. What Boards does FDA recognize for interpreting physicians?

A. The FDA recognizes physicians certified with specialties in diagnostic radiology by the following organizations:

- American Board of Radiology (ABR)
- American Osteopathic Board of Radiology (AOBR)
- Royal College of Physicians and Surgeons of Canada (RCPSC).

Q2. What Boards does FDA recognize for medical physicists?

A. The FDA recognizes physicists certified with specialties in diagnostic radiological physics or radiological physics by the following organizations:

- American Board of Radiology (ABR)
- American Board of Medical Physics (ABMP).

Q3. What Boards does FDA recognize for radiologic technologists?

A. The FDA recognizes technologists certified by the following organizations:

- American Registry of Radiologic Technologists (ARRT)
- American Registry of Clinical Radiography Technologists (ARCRT) if the technologist is now registered with the ARRT.

Q4. What qualifications must an interpreting physician have?

A.
(i) A valid state license to practice medicine;*and*
(ii) (a) Evidence of certification by the American Board of Radiology (ABR), American Osteopathic Board of Radiology (AOBR), or Royal College of Physicians and Surgeons of Canada (RCPSC) in diagnostic radiology (original or copy of certificate, letter from one of the above boards or college, or a letter from the American College of Radiology (ACR) specifically confirming that the physician is board certified by the ABR or the AOBR, will be acceptable documentation);*or*
(b) 2 months of documented training in mammography;*and*
(iii) Documented 40 hours CME in mammography;*and*
(iv) Initial experience:

Documented experience in reading/interpretation of mammograms from at least 240 patients in the 6 months preceding the facility's application to an accreditation body or during any 6 months prior to October 1, 1994, or after October 1, 1994, in any 6-month period under the supervision of a qualified interpreting physician; *and*

(v) Continuing experience and education:
   (a) Documented continuing experience showing that the required average of at least 40 examinations per month (when averaged over the 24 months prior to the inspection date, or over the period from October 1, 1994, to the inspection date, whichever is shorter) have been read/interpreted by the individual; *and*
   (b) Documented average of 5 CME credits/year in mammography. This average will be required beginning 3 years from October 1, 1994, or from the date of initial qualification whichever is later. If documentation is not available, proper attestation will be acceptable for items (iii) and (iv) for records dated up to October 1, 1994.

Q5. Is there an alternative for interpreting physicians who are not certified by an approved board?

A. Yes. They may present evidence of at least 2 months of full-time training in the interpretation of mammograms, including instruction in radiation physics, radiation effects, and radiation protection. Again, this is an alternative only to the board certification requirement. They must also meet the licensing, training, and experience requirements (as must board-certified physicians).

Q6. What constitutes 2 months of documented full-time training as an alternative pathway to qualify as an interpreting physicians ?

A. FDA has developed the following guidelines for MQSA inspectors to use in determining whether the documented 2 months of training, as a satisfactory alternative process of becoming qualified as an interpreting physician requirement, has been met.

1. A letter or other documentation from the physician's American or Canadian residency program documenting that the physician has met the 2 months of training in mammography. The letter can come from either the current officials or from those in authority at the time of the physician's residency. It must come from a responsible residency program official who has the authority to sign for the department.

2. Documented CME in mammography totaling 280 hours, which may include certificates, letters, etc. These CME units must be category I (recognized by

the Accreditation Council for Continuing Medical Education [ACCME], American Osteopathic Association Continuing Medical Education [AOA CME], American Medical Association Physician's Recognition Award [AMA PRA], state medical society), or equivalent.

3. Documentation of successful completion of formal mammography training courses (recognized by the ACCME, AOA CME, AMA PRA, state medical society), or equivalent.

4. Documentation of formal training in radiation physics, radiation effects, and radiation protection may be used to satisfy up to 90 hours of the total 280 hours training requirement. At least two-thirds of the training must be devoted to interpretation of mammograms.

5. Documentation establishing that a combination of the physician's residency training, formal training, and CME total the equivalent of 2 months (280 hours).

Q7. Under MQSA, is there a required number of mammograms that an interpreting physician needs to read?

A. Yes. The interpreting physician must read the films from the examination of an average of at least 40 patients per month over 24 months. This requirement begins October 1, 1994, or on the date the physician initially qualifies as an interpreting physician, whichever is the latest. To meet this requirement, interpreters may double read films previously read by other interpreters, read films used in educational programs, or read films in more than one facility.

Q8. If a radiologist is reading a mammogram taken previously and is comparing the study with current mammograms, for how many cases does this count?

A. It depends upon whether the radiologist did the original interpretation of the old mammograms. If he or she did not do that interpretation, both the old mammograms and the current images are new to him or her and this would count as two cases (the re-reading of the older images would be an example of what we mean by double reading). On the other hand, if the radiologist was the one who originally interpreted the older films, those images could not be counted again and only the current study would count towards the required average.

Q9. What documentation must I have for (1) the requirement that physicians have read and interpreted the mammograms from the examinations of at least 240 examinees in a 6-month period, and (2) the requirement for continuing to read

and interpret mammograms from the examinations of an average of at least 40 examinees per month over 24 months?

A. If the first requirement was met before October 1, 1994, data from the facility involved showing the number read, or an attestation from the physician involved, would be sufficient. If the first requirement was or will be met after October 1, 1994, a signed statement from the supervising physician attesting that it was met must be available. For the continuing experience requirement, starting October 1, 1994, facilities will be expected to provide documentation of monthly totals.

Q10. How can a physician reestablish his/her continuing experience requirement if that physician fails to meet the continuing experience requirement of reading and interpreting mammograms from an average of 40 examinations per month, averaged over a 24-month period ?

A. Interpreting physicians must meet the MQSA continuing experience requirement to read and interpret mammograms from an average of at least 40 examinations per month, averaged over a 24-month period. Presently, this requirement is not in effect because 24 months from October 1, 1994 will not have passed until October 1, 1996?

Interpreting physicians who fail to meet this continuing experience requirement must reestablish their qualifications by reading and interpreting mammograms from a number of examinations **under direct supervision** before resuming independent reading. The number of examinations that must be read and interpreted under direct supervision is the lesser of :

1. A sufficient number to bring the physician's average up to 40 examinations per month in the previous 24-month period, *or*

2. Mammograms from 240 examinations.

Item #1 or #2 must be accomplished within six months of the requirement being imposed. This policy does not affect the date on which such individuals met the initial qualifications requirements.

Q11. An interpreting physician read and interpreted mammograms from an average of 38 examinations per month over the past 24 months. How can he/she reestablish continuing experience requirement?

A. By reading mammograms from 48 examinations **under direct supervision** within the next six month period, he/she can reestablish his/her qualificatins under the

continued experience requirement and may then begin reading and interpreting mammograms independently.

Q12. ***An interpreting physician read and interpreted mammograms from an average of only 12 examinations per month over the past 24 months. How can he/she reestablish continuing experience requirement ?***

A. By reading mammograms from 240 examinations**under direct supervision** within the next six month period, he/she can reestablish his/her qualifications under the continued experience requirement and may then begin reading and interpreting mammograms independently.

Q13. ***We presently have on site a printout documenting the number of cases read per individual radiologist. Can we replace this with a computer diskette that can be viewed on-site?***

A. Yes.

Q14. ***The requirements for interpreting physicians indicate interpreters can double read films. What does double read mean?***

A. Double read means read films previously read by a different interpreting physician. (See Question 7.)

Q15. ***What documentation must I maintain for our radiologists for training and education?***

A. Copies of certificates earned or other documentation from the training provider will suffice. For training received before October 1, 1994, if no other documentation is available, proper attestation may be used. However, attestation may**not** be used to document that the doctor satisfies the alternative to board certification, which is to have at least 2 months of full-time training in mammography. (See Questions 4 & 5.)

Q16. ***Is it still mandatory that the supervising radiologist observe each mammography technologist once a month?***

A. No, not after October 1, 1994.

Q17. If a qualified interpreting physician and an interpreting physician-in-training (one being supervised to meet the initial experience requirement of at least 240 mammograms in the past 6 months) read a mammogram, who should sign the report?

A. At the minimum, the qualified interpreting physician must sign the report. Both can sign so long as it is clear the interpreting physician-in-training is supervised by the qualified interpreting physician.

Q18. What qualifications must a medical physicist have?

A.
(i) (a) State license/approval; *or*
(b) Certificate with a specialty in diagnostic radiological physics or radiological physics from the American Board of Radiology (ABR) or American Board of Medical Physics (ABMP);*or*
(c) Before October 27, 1997, have a masters or higher degree in physics, radiological physics, applied physics, biophysics, health physics, medical physics, engineering, radiation science, or in public health with a bachelor's degree in physical sciences;*and*
(1) 1 year documented training in diagnostic radiologic physics,*and*
(2) 2 years documented experience in mammography surveys;*and*
(ii) Documented average of 5 CEUs per year in mammography. If documentation is not available, proper attestation will be acceptable for (i)(c)(1) and (2) for records dated up to October 1, 1994.

Q19. What qualifications must a technologist have?

A.
(i) A valid state license or certificate from the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT) (radiologic technologists certified by ARCRT must be additionally registered by ARRT);*and*
(ii) Documented specific mammography training or, until October 1, 1996, 1 year experience in performing mammography;*and*
(iii) A documented average of 5 CEUs per year in mammography. This average will be required 3 years from October 1, 1994, or from the date of initial qualifications whichever is later. If documentation is not available, proper attestation will be acceptable for item (ii) for records dated up to October 1, 1994.

Q20. Must radiologic technologists pass the ARRT mammography special competency exam to perform mammography exams?

A. No. However, passing the ARRT mammography special competency examination is viewed by FDA as meeting the training requirement.

Q21. ***I began working as a technologist at a mammography facility after completing training in June 1991 that included courses and experience in conducting mammography examinations. I have not received any CEUs since May 1993. Must I stop performing mammography until I receive further training?***

A. No. But you are required to earn at least 15 CEUs in mammography between October 1, 1994, and October 1, 1997.

Q22. ***I am a radiologic technologist who has previously taken an American Cancer Society course on breast self-examination. I have two questions about this training in regard to MQSA and my CEU requirements: (1) Can I take the test only for this class because I've taken the class in the past and would prefer not to repeat the training? (2) Can I apply the credits I earn from this class to my mammography training or CEUs?***

A. Although this course relates to breast examination and care, it does not, however, directly relate to mammography. Therefore, we would suggest that this course be applied on a one-time basis to mammography training credits (not CEUs). If you choose to take only the test and pass, the credits you earn may be applied to your mammography training but not be applied to CEUs.

Q23. ***Does MQSA require that the name of the technologist performing the mammogram be included in the written interpretation?***

A. No.

Q24. ***If a technologist is seeking to satisfy the initial training requirement by obtaining 40 hours of training, must she/he also earn separate CEUs to satisfy the continuing education requirement?***

A. As a general rule, personnel are not allowed to double count their training, that is, use the same hours of training to satisfy both the initial and the continuing education requirements. However, technologists who, at first, meet the initial training requirement using the experience alternative and then maintain their status by receiving at least 40 hours of training in mammography before October 1, 1996, are in a unique situation. For this reason, FDA will permit such technologists to also count toward the continuing education requirement any part of the 40 hours received after the date at which they satisfied the initial requirements using the

experience alternative. For example, a technologist who had 20 hours of training in mammography on October 1, 1994, but was able to continue to work independently because she met the experience requirement, can maintain her qualifications after October 1, 1996, by receiving an additional 20 hours of training by that date. If she chooses that route, the additional 20 hours will also count toward her continuing education requirement.

Q25. Does the FDA accept a Mammography Radiologic Technology Certificate from the State of California as evidence that the technologist has met the initial training requirement in mammography?

A. Yes. The California criteria for receiving a Mammography Radiologic Technology Certificate meet or exceed the previous MQSA guidance (refer to Q25, following) for determining if the technologist has adequate initial training in mammography. Therefore, a technologist who has earned such a certificate can be considered to meet the MQSA initial training requirement.

Q26. Does the FDA accept a Mammography Certificate from the State of Arizona as evidence that the technologist has met the initial training requirement in mammography?

A. Yes. The Arizona criteria for receiving a Mammography Certificate meet or exceed the previous MQSA guidance (refer to Question 25) for determining if the technologist has adequate initial training in mammography. Therefore, a technologist who has earned such a certificate can be considered to meet the MQSA initial training requirement. However, a temporary Arizona certificate cannot automatically be accepted as evidence of adequate initial training. The training of the holder of a temporary Arizona certificate must be evaluated individually to determine if it is adequate.

Q27. If a technologist allows his or her ARRT(M), California Mammography Radiologic Technology Certificate, or Arizona Mammography Certificate to expire, can the expired credential be accepted as evidence that the initial training requirement has been met?

A. Yes, because training does not expire. Thus, even if a technologist allows his or her ARRT(M), California Mammography Radiologic Technology Certificate, or Arizona Mammography Certificate to expire, the expired credential still can be accepted as evidence that the initial training requirement has been met. In contrast, general licenses or certificates must be kept valid to meet the license or certificate requirement for technologists.

Q28. Can a California Mammography Radiologic Technology Certificate or an Arizona Mammography Certificate be accepted by other states as evidence that a technologist has had adequate training in mammography?

A. Yes. Although these credentials are called certificates, in accordance with California practice, they are considered licenses under MQSA because they come from a government body. In accordance with the general MQSA policy that a license from a state satisfies the MQSA requirement in all states, the California Mammography Radiologic Technology Certificate and Arizona Mammography Certificate should be accepted in all states, not just California or Arizona, as evidence of adequate technologist training in mammography under MQSA.

Q29. What does the FDA accept as evidence that a technologist has met the initial training requirement in mammography?

A. A technologist can now be considered to meet the MQSA initial training requirement if he or she possesses any*one* of the following:

(i) A California Mammography Radiologic Technology Certificate,
(ii) An Arizona Mammography Certificate,
(iii) An ARRT advanced certificate in mammography,
(iv) At least 40 hours of training in mammography,*or*
(v) Evidence of successful completion of the Medical Technology Management Institute (MTMI) 3-day mammography course for technologists.

These criteria are only guidance, not regulation. If a technologist does not meet any of the five, his or her training may still be adequate and must be evaluated individually.

Q30. Are radiologic technologists required to be licensed by a state or certified by an FDA-approved body? Can further requirements be mandated by a state?

A. Yes. A general state technologist license or a general certificate from the ARRT will still be required to meet the first MQSA technologist requirement, which is to be licensed by a state or certified by an approved FDA body. As always, states are allowed to enforce more rigorous requirements under their own authority.

Q31. Will the FDA accept attestation for CME/CEU earned after October 1, 1994, if the provider of the training does not specifically document that the training was in mammography? If so, what procedure must be followed?

A. FDA will continue to accept a limited form of attestation beyond October 1, 1994, in situations where the training provider does not specifically document that the

training offered at a meeting, or other training opportunity, was in mammography. To use CME/CEU earned from such providers to meet the initial or continuing education requirements, the physician, technologist, or medical physicist will have to provide:

1. Documentation from the CME/CEU provider of the total number of CME/CEU he/she earned at the meeting.

2. Documentation (for example, meeting agendas) showing the number of hours he/she could have earned in mammography at the meeting.

An individual providing such documentation will then be allowed to attest (using FDA's recommended form or a form with similar elements) to the number of CME/CEU in mammography he/she actually earned at the meeting, assuming that the CME/CEU he/she claims, does not exceed either of the numbers documented in 1 and 2 above.

The above policy applies only in cases where there are opportunities to earn CME/CEU in several fields at the same event. If the meeting or other training opportunity is limited strictly to mammography, then all that would be needed would be the documentation from the provider of the number of CME/CEU earned.

Q32. If a technologist fails to obtain adequate training by October 1, 1996, should he/she stop performing mammography ?

A. Yes. A technologist, who has been using the experience alternative to training in mammography, must obtain adequate training in mammography by October 1, 1996. If the technologist fails to obtain adequate training by that date, he/she must cease performing mammography until such training is obtained.

Q33. If a technologist must cease performing mammography for a period of time after October 1, 1996, for the reason stated above, what should be used as the starting date for him/her to begin meeting the continuing education requirement?

A. The original starting date for meeting the continuing education requirement will be used for the technologist in this situation.

Q34. The American Registry of Radiologic Technologists (ARRT) has stated that earning the advanced certificate in mammography (ARRT[M]) is equivalent to earning 24 continuing education units. May a technologist, who had been using the experience alternative to training in mammography and now has satisfied the

training requirement by earning the ARRT(M), count those 24 units towards his/her continuing education requirement?

A. Yes. The FDA has concluded that technologists who have been using the experience alternative to training and who now have met the training requirement by earning the ARRT(M) should also be allowed to count the 24 continuing education units towards their continuing education requirement.

This policy is consistent with the fact that technologists, who met the training requirement on October 1, 1994, (thus did not need to use the experience alternative) and who later earned the ARRT(M), can already count the 24 hours towards their continuing education.

HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Q1. ***How does the HCFA process relate to the FDA certification and accreditation process?***

A. HCFA has revised its regulations so that since October 1, 1994, a facility that meets the MQSA quality standards has been considered as meeting the HCFA requirements related to quality. HCFA also accepts MQSA inspections in lieu of conducting its own inspections. Thus, as long as a facility has an FDA certificate under MQSA, HCFA will reimburse it for Medicare-covered screening and diagnostic mammography examinations. HCFA will not reimburse facilities that do not have an MQSA certificate. The amount and frequency of reimbursement will still be governed by the HCFA regulations.

Q2. ***I need clarification on the new physician standard. In an "off-site" mammography setting, is the radiologist required to do any "on-site" inspections, or is it acceptable for the "off-site" technologist to visit the facility housing the physician?***

A. You are asking about the HCFA physician consultant standards, specifically, where can the interpreting physician observe the technologist performing an examination. Under the interim final MQSA regulations, there is nothing equivalent to the HCFA physician-consultant standards; thus, the technologist will not have to be observed in either the "off-" or "on-" site settings.

Q3. ***My facility was previously cited following a HCFA mammography inspection and I have subsequently received my FDA certificate for MQSA. Does the fact that we now have our FDA Certificate supersede the HCFA inspection? Do I still have to fulfill HCFA requirements?***

A. HCFA published a Federal Register notice on September 30, 1994, [59 FR 49826] stating that after October 1, 1994, a facility will have to have an FDA Certificate for Medicare reimbursement for screening and diagnostic mammography. This means that the HCFA facility regulations and inspections have been replaced by the FDA regulations and inspections. Facilities will still need to use their HCFA provider number and follow the HCFA rules with respect to the frequency and amount of payment, and how to apply for that payment. However, your FDA Certificate is evidence that you are meeting the necessary quality standards.

Q4. At what point can a certified mammography facility claim reimbursement under MQSA?

A. October 1, 1994, was the date on which facilities could begin to submit HCFA reimbursement claims for mammography services under MQSA. For those facilities who apply for accreditation and FDA certification after October 1, 1994, they can begin to submit HCFA reimbursement claims for mammography services under MQSA based on the date on which their accreditation body notified them that their application was complete for review.

Q5. What information must I submit to HCFA to get mammography reimbursement from HCFA?

A. You need to submit FDA's facility ID # on the FDA certificate by the expiration date.

CONSUMER COMPLAINT MECHANISMS

Q1. What provision has been made for consumer complaints under the interim regulations?

A. The interim regulations address complaints under the section entitled, "Responsibilities of Accrediting Bodies." Under the interim regulations, the accrediting body is required to publish an address for filing complaints, investigate complaints within 90 days of receipt, and maintain records for a period of 3 years. A consumer complaint mechanism will be published as part of the final regulations.

MOBILE UNITS

Q1. What are the requirements for certification of mobile units?

A. Certification requirements for mobile units are the same as the requirements for fixed-facility units. They must be accredited by an FDA-approved accrediting body. If a mobile provider maintains and operates several units from the same central location, those units may be eligible for a single accreditation and certification just as multiple units in a single facility would be covered by one certificate.

Q2. Does a mobile unit need to include a film processor?

A. No. A mobile unit does not need to include a film processor. However, any processor used for films taken by the unit must be identified and is subject to MQSA inspections for verification that the equipment meets quality standards.

Q3. We have more than one mobile unit that we take into several hospitals and clinics. Consequently, we have several different waiting areas. How do we display one certificate?

A. Mobile units can get additional (duplicate) certificates, each of which will reflect the unique identification number of the facility with which they are associated.

Q4. What would represent an appropriate method for repeat analysis for my mobile service, for example, independent analysis for each facility, a combined analysis for all sites, etc.? A majority of our images are processed at the facility where the images are produced, while some images are processed at our base facility. Also, what frequency would be recommended, for example, 250 films per facility or program, quarterly or monthly, etc.?

A. To be effective, the reject analysis must be facility based and not combined. The analysis must be done at least quarterly (if possible including at least 250 examinations).

RECORDKEEPING

Q1. What constitutes a medical record under MQSA?

A. Although there can be many documents that are legally part of the medical record, MQSA is concerned with mammograms (the films) and the mammography reports.

Q2. How long must facilities retain examinee medical records?

A. Each facility must maintain mammograms and associated records in a medical record of the examinee: (1) for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the examinee are performed at the facility, or longer if mandated by state or local law;*or* (2) until requested by the examinee to permanently transfer the records to a medical institution, or to a physician of the examinee, or to the examinee, and the records are so transferred.

Q3. Do mammograms have to be kept on site?

A. No. They may be maintained at an off-site film library or storage area.

Q4. Can mammograms be sent to referring physicians for them to keep?

A. Yes, provided the patient has signed a release to allow her referring physician to keep the films.

Q5. Do facilities have to respond to requests to send films to other institutions for comparison studies?

A. Under the interim regulations, MQSA has no requirement for facilities regarding transfer of films for comparison studies. Thus, it is up to the facility to have its own comparison transfer policy. Copies or originals can be sent. If copies are sent, FDA recommends these be of high quality because surgical decisions may be made based on these copies. MQSA only covers permanent record transfer, not temporary transfers of comparison studies.

Q6. Can examinees request to keep their own films and reports?

A. Yes. Examinees can request a facility to transfer records permanently to another facility, medical institution, physician, or themselves.

Q7. What requirements does a facility have to meet in reporting the results of a mammogram?

A. Each facility should prepare a written report of the results of any mammography examination as soon as reasonably possible. The report must have the name of the interpreting physician, and this report must be provided to the examinee's physician, if any. If the examinee does not have a physician, the report shall be sent directly to the patient. In such a case, it shall include a summary written in language easily understood by a lay person.

Q8. What does "signed by an interpreting physician" mean? Is an actual signature required?

A. FDA does not require an actual signature, but simply that the name of the interpreting physician be on the medical report. The name identifies who has seen and read the mammogram and who is responsible for the interpretation. A report must have the minimum information of first initial and the last name of the physician who is responsible for the interpretation.

Q9. Does MQSA require that the name of the technologist performing the mammogram be included in the written interpretation?

A. No.

Q10. When do examinees get the mammography reports?

A. Under MQSA, examinees who do not have a referring physician (self-referred examinees) should get the mammography report and<u>a summary of the report in lay terms</u>. This permits examinees who have no primary care doctor, but who later acquire one, to give their new doctor their latest mammogram results. Self-referred patients with abnormal results need to be able to show their new physician exactly what is wrong and what the radiologist has recommended.

Q11. What is meant by the term "self-referred" examinee/patient?

A. Self-referred examinees/patients who do not have referring physicians/health care providers, under MQSA, will receive their mammography results. They are responsible for their own appropriate follow-up health care. Specific examples of examinees/patients who are NOT self-referred include:

1. Examinees/patients who come to the facility without a physician's/health care provider's referral, but tell the facility to which physician/health care provider they wish the report to be sent.

2. An examinee/patient who comes to the facility without having a physician/health care provider, but is willing to accept a physician/health care provider recommended by the facility and understands that her mammogram report will be sent to that physician/health care provider. In some cases, the radiologist can also act as the referring physician, as long as he/she accepts responsibility for the examinee's/patient's medical care and this is acceptable to the examinee/patient.

Q12. How do these reporting requirements under MQSA differ from those used previously by HCFA?

A. Under the HCFA requirements, a report in lay language had to be sent to all Medicare examinees. Under the MQSA regulations, this is required only for examinees who have no health care provider or referring physicians.

Q13. Are facilities required to collect follow-up clinical outcome data on mammograms?

A. Yes. Facilities are required to "establish a system for reviewing outcome data from all mammographies performed. . . ." Currently, FDA only inspects on the clinical follow-up of positively interpreted mammograms (positive mammograms mean those interpreted as highly suggestive of cancer; possibly cancer; surgical consultation recommended to rule out cancer; biopsy suggested to rule out cancer). Therefore, outcome data must be collected on all positive mammograms. The system can be a manual system or involve one of the many computer software programs that have been developed for this purpose. No specific system is required by the regulations; the facility is free to choose or develop a system that best fits its needs. However, an adequate follow-up system is one that has potential to obtain pathology information on all patients with positive mammograms. If a facility enters all positive mammograms into a log, but does not gather pathology information of all these women, then the facility is said to have a mechanism of tracking positive mammograms but not an adequate follow-up system. Such a

system, therefore, does not have the potential to obtain clinical information on all positive patients. Under current MQSA inspection procedures, at a minimum, the facility must record the names of all the examinees with positive mammograms and then attempt to track them. The minimum clinical information a facility must obtain is whether a biopsy was benign or malignant. However, FDA understands that the clinical information may not be available for variety of reasons, including the unwillingness of the patient or referring physician to release the information. Nevertheless, facilities that take the time to explain the benefits of tracking, as it pertains to quality assurance, often find that the patients and physicians are willing to cooperate.

Q14. What is a "system for reviewing outcome data"?

A. A facility must have a set of procedures to track, at least, the positive mammograms and determine if biopsies were done and whether the results of the biopsies were benign or malignant. This information should be given periodically to the interpreting physician so that he or she can learn from biopsy results and correlate biopsy results with interpretations. This is a way to provide quality assurance for interpretations. Not all films need be tracked, but at a minimum, it is necessary to track positive mammograms. FDA recognizes it is difficult to track biopsy results and that this information requires the cooperation of referring physicians and laboratories. Therefore, MQSA inspectors will not be verifying the completeness of outcome data, only that a tracking system is in place and being used.

Q15. What will the MQSA inspectors look for in a medical outcomes audit inspection?

A. The inspectors will be asking a facility to document the answers to the following questions:

1. Is there an audit system?
2. Are all positive patients entered in the system?
3. Is there the potential to obtain all pathology results?
4. Are biopsy results present or attempts to obtain this information documented?

Biopsy results, either obtained by phone or copied from an actual reports, can be used to document item number 4.

Q16. Under MQSA, who would be cited for failure to obtain follow-up information for the clinical outcomes audit system?

A. The facility, meaning the certificate holder, which is usually an organization such as a radiology department, is the responsible party.

Q17. Must a facility use computerized programs for tracking and outcomes data?

A. No. A facility can use a manual system.

Q18. If my facility does not use the ACR's software product for clinical outcome audits, will my facility be penalized?

A. No. The facility is free to choose the system, manual or computerized, that best fits its needs. No specific system is required and if any vendor should imply, either orally or in their literature, that his or her system is required, the FDA should be informed immediately, so that the Agency can take appropriate action.

Q19. Must a tracking system for outcomes analysis be on site?

A. No. Several facilities can share a single tracking system, and this system does not have to be on site. The States of Colorado and Vermont have tracking being done by the State Health Department. This system will track outcomes for 20-50 facilities. This is a perfectly acceptable system. Each facility must be provided with its patient results and, preferably, the cases are identified by interpreting physician so that feedback to individual physicians is possible.

Q20. What statistics are facilities required to collect?

A. As of now, FDA is not establishing specific requirements, although the agency expects to do so over the next few years. Right now, a facility just needs to have a system to collect outcome information. There are several articles in radiology journals that describe what data can be collected in a facility's medical audit. In 1997, FDA will publish final regulations for MQSA that will tell facilities more about what will be required for a medical audit.

Q21. Do facilities have to collect biopsy results? Staging? Size of tumors?

A. At a minimum, a facility should collect data on whether the tissue sample is benign or malignant. Of course, more pertinent information will permit a facility to better evaluate its success in early detection of breast cancer. Several articles have been published in radiology journals describing what biopsy data should be collected.

Q22. How long must I keep QC records for my facility?

A. All facilities are expected to retain all QC records for 1 year starting October 1, 1994 (exception: daily sensitometry films only need to be retained for at least the last 30 days during which the mammograms were processed). This will give the inspector and the medical physicist the opportunity to review the facility's QC history.

HISTORY

Q1. Why did Congress pass the MQSA?

A. The motivation for the passage of MQSA was public response to concerns about breast cancer and about the quality of the mammography services being relied upon for the early detection of breast cancer. Congress passed MQSA to assure that women have access to high-quality mammography in our nation's battle against breast cancer. In MQSA, Congress provided for a number of regulatory measures designed to improve the quality of mammography.

Q2. What was the effective date of MQSA?

A. October 1, 1994.

QUALITY ASSURANCE

Q1. What are the quality assurance requirements under MQSA?

A. The quality assurance requirements are contained in the interim standards, published in the Federal Register in December 1993 and September 1994. For screen-film units, the quality assurance program must be "substantially the same as" that described in the 1992 or 1994 edition of the American College of Radiology's quality assurance manuals.

Q2. What quality control tests are required for Xerox units?

A. For systems with alternate image receptor modalities (at present only xeromammography), the quality assurance program must be substantially the same as that recommended by the image receptor manufacturer.

GENERAL QUESTIONS

Q1. ***I am a consumer. How do I know if my facility is certified?***

A. Look for an FDA mammography facility certificate.

Q2. ***As a consumer, what does the FDA mammography facility certificate mean to me?***

A. Display of a certificate by a facility means that it has been certified as meeting minimum national standards of quality in mammography.

Q3. ***When must a facility begin to display the FDA certificate?***

A. As soon as they become certified and prior to performing mammography on patients.

Q4. ***If I want to find out information about either an individual facility or facilities in my area, is there a way I can get this information?***

A. Yes, you may secure limited information of this nature. If you wish to locate certified facilities in your area, you may contact the National Cancer Institute at 1-800-4- CANCER (1-800-422-6237).

Q5. ***I am a consumer and want to find out more about mammography. Whom do I call?***

A. The "hotline" for consumer calls is 1-800-4-CANCER (1-800-422-6237).

Q6. ***I heard there is an address where I can write and get literature on mammography and breast cancer. Is this true and if so, what is the address?***

A. For more information about mammography guidelines or to receive written materials, call 1-800-358-9295 or write:

Agency for Health Care Policy and Research
Publications Clearinghouse
P.O. Box 8547
Silver Spring, MD 20907.

Q7. When will the MQSA Final Rules for facilities and accreditation bodies be published?

A. The MQSA Final Rules are under development and have already been discussed with the National Mammography Quality Assurance Advisory Committee. The goal is to publish proposed final regulations for public comment in the Federal Register in the Spring of 1996 and to publish the final regulations in the Spring of 1997. A transition period will be provided after the publication of the final regulations before the regulations go into effect.

Q8. The Department of Veterans Affairs (DVA) is excluded from MQSA accreditation requirements? Why?

A. During the time MQSA was being considered by the Congress, the inclusion of DVA facilities would have required consideration by additional subcommittees and would have delayed passage of the statute.

Q9. To what standards does the Department of Veteran Affairs (DVA) comply?

A. Although DVA is not covered by MQSA, it has developed a similar program of their own.

Q10. I heard the Bureau of Prisons is exempt from MQSA. Is this true?

A. No. Only DVA is exempt.

EQUIPMENT:

To be added.

INDEX